IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CYTIVA BIOPROCESS R&D AB and)	
CYTIVA SWEDEN AB,)	
)	
Plaintiffs,)	
)	
v.)	C. A. No. 21-310 (RGA)
)	
JSR CORPORATION, JSR MICRO NV)	
and JSR LIFE SCIENCES, LLC,)	
)	
Defendants.)	

LETTER TO THE HONORABLE RICHARD G. ANDREWS IN OPPOSITION TO PLAINTIFFS' LETTER REGARDING LIFTING STAY (D.I. 79)

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Attorneys for Defendants

Dear Judge Andrews,

Defendants JSR Corporation, JSR Micro NV, and JSR Life Sciences, LLC (collectively, "JSR") oppose Cytiva's request to lift the stay of the above-captioned matter. *See* D.I. 70. The stay should remain in place through the pending appeals of the IPRs to the Federal Circuit, because (i) those appeals will streamline the issues before this Court, if not entirely obviate the need for further litigation, (ii) this case is in its early stages, and (iii) Cytiva will not suffer undue prejudice.

I. Background on the Parties' Dispute

This case involves a tool, namely a *staphylococcal* protein A ("SPA") affinity chromatography matrix, that can be used to purify antibody-based therapeutics. This matrix is generally constructed with an SPA-based ligand (having affinity for target antibodies) coupled to a solid support bead packed into a column. When antibodies and other materials move through the column, the antibodies bind to the ligand (*i.e.*, SPA) portion of the chromatography matrix while non-desired materials wash away. It is undisputed that Cytiva has had the largest market share for the sale of SPA chromatography matrices in the industry for decades, while JSR is a relatively recent entrant to the market.

Cytiva filed suit in February 2021, asserting that JSR has infringed three patents of the same family. One of those patents (U.S. Patent No. 10,213,765) is directed to the physical structure of an SPA chromatography matrix. The other two patents (U.S. Patent Nos. 10,343,142 and 10,875,007) are directed to methods of using the SPA chromatography matrix claimed in the '765 patent. Cytiva does not practice the claims of the asserted patents.

On October 12, 2021—less than two weeks after Cytiva served its infringement contentions asserting 83 claims of the asserted patents—JSR filed six IPRs¹ challenging the validity of all asserted claims. The PTAB instituted IPR of all challenged claims, and the parties later jointly stipulated to stay this case pending the PTAB's final written decisions. *See* D.I. 67.

The PTAB has since found that all but four of the 83 asserted claims are unpatentable, including all asserted claims of the '765 patent.² The four surviving claims all recite one identical limitation: "wherein the ligand binds to the Fab part of an antibody." *See D.I.* 1-1, '142 patent, claims 4 and 17, '007 patent, claims 11 and 29. In recent weeks, Cytiva has appealed the PTAB's decisions invalidating 79 claims. JSR has likewise cross-appealed the PTAB's decisions with respect to the four surviving claims.

¹ See IPR2022-00036 (challenging validity of '765 patent claims); IPR2022-00043 (same); IPR2022-00041 (challenging validity of '142 patent claims); IPR2022-00044 (same); IPR2022-00042 (challenging validity of '007 patent claims); IPR202200045 (same).

² See IPR2022-00036, Paper 41 (Apr. 19, 2023); IPR2022-00043, Paper 44 (Apr. 19, 2023); IPR2022-00041, Paper 40 (May 18, 2023); IPR2022-00044, Paper 43 (May 18, 2023); IPR2022-00042, Paper 40 (May 18, 2023); IPR2022-00045, Paper 43 (May 18, 2023).

II. The Court Should Exercise Its Discretion to Continue the Stay Pending Resolution of the Federal Circuit Appeals

All three relevant factors weigh in favor of continuing the stay. See Novartis AG v. HEC Pharm Co., 183 F. Supp. 3d 560, 562 (D. Del. 2016) ("The factors courts typically consider in deciding how to exercise this discretion include: (1) whether a stay will simplify the issues and trial of the case, (2) whether discovery is complete and a trial date has been set, and (3) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party.").

Simplification. Cytiva's appeals seek to revive 79 claims, while JSR's cross-appeals seek to eliminate the four surviving, identical claims. Because "both parties are appealing all of the PTAB's decisions adverse to their respective positions," staying these cases pending appeal would likely eliminate or at least simplify the issues in this case. See Masimo v. Apple Inc., No. 20-cv-00048, D.I. 786 at 4-5 (C.D. Cal. June 23, 2022) (citations omitted) (Ex. A). In comparison, under Cytiva's piecemeal proposal—i.e., moving forward on just four claims now, while later bringing in 79 other claims should it succeed on appeal—there is significant risk of duplicating the resources of the Court and the parties. See, e.g., eBuddy Tech. BV v. LinkedIn Corp., No. 20-1501, D.I. 152 (D. Del. July 31, 2023) (maintaining stay where plaintiff appealed PTAB decisions invalidating all claims of two of the four asserted patents, yet sought to proceed on the two remaining patents despite defendants' appeal of those decisions, explaining that "the Court is not going to turn one case into two cases"); Cellwitch Inc. v. Tile, Inc., No. 19-1315, 2021 WL 9145413, *2-*4 (N.D. Cal. Oct. 8, 2021) (maintaining stay where both parties appealed PTAB decisions finding some claims unpatentable and upholding others).

If the stay is lifted and the Federal Circuit were to rule in JSR's favor, all asserted claims will be cancelled as unpatentable—the "ultimate simplification of issues." *VirtualAgility Inc. v. Salesforce.com, Inc.*, 759 F.3d 1307, 1314 (Fed. Cir. 2014). If Cytiva prevails, the number of claims at issue could increase nearly twentyfold and the parties and the Court would likely need to redo significant portions of this case, including discovery and claim construction, among other inefficiencies. To say the least, the appeals could drastically impact the scope of this case.

Moreover, plowing ahead on the four surviving claims makes little sense in light of the issues on appeal, which will have implications on numerous issues here, including claim construction and JSR's § 112 and noninfringement defenses. For example, two of the 79 invalidated claims are drawn to an SPA chromatography matrix comprising a ligand defined by a particular amino acid sequence that is capable of binding to the "Fab part of an antibody." The PTAB determined that JSR had shown these claims to be unpatentable for reciting an inherent property of an otherwise obvious claim. All that the surviving four claims do is recite this inherent Fab binding-related property in the context of a method of purification (with no other claim limitations added). Continuing the stay of this litigation to allow the Federal Circuit to weigh in on these important issues will either entirely obviate the need for any further litigation, or at a minimum, streamline and simply the issues for litigation. See, e.g., AgroFresh Inc. v. Essentiv LLC, Case No. 16-662, 2019 WL 2327654, at *2 (D. Del. May 31, 2019) (finding this factor favors a stay when simplification applies to a substantial part of the case); DivX, LLC v. Netflix, Inc., Case No. 19-1602, 2022 WL 1208167, at *5 (C.D. Cal. Mar. 29, 2022) (stating that "maintaining the stays pending appeal is likely to simplify the issues in these cases and could avoid unnecessarily wasting party and judicial resources, particularly as to claim construction").

Stage of the Case. Cytiva contends that this case is not in its early stages (D.I. 79 at 2), but took the exact opposite position in a statement to the Federal Circuit three weeks prior (Ex. B at 2 (stating that the "district court litigation . . . is in its early stages")). Cytiva was right the first time. At the time the stay was entered on May 11, 2022, the parties had not reached the deadline for substantial completion of document production, and no fact depositions had occurred. Moreover, almost one year remained until the close of expert discovery, and trial was approximately 18 months away. Given the most burdensome stages of the case lie ahead, this factor favors a stay. See, e.g., Pers. Genomics Taiwan, Inc. v. Pac. Biosciences of California, Inc., Case No. 19-1810, 2022 WL 4245532, at *2 (D. Del. Sept. 15, 2022) (granting motion to stay pending appeal of the IPR decision where fact discovery had not closed and no depositions had been taken); Brit. Telecomms. PLC v. IAC/InterActiveCorp, Case No. 18-366, 2019 WL 4740156, at *4 (D. Del. Sept. 27, 2019).

No Undue Prejudice. Cytiva will not suffer undue prejudice if the stay is maintained. Contrary to Cytiva's assertion, the "potential for delay . . . is insufficient to establish undue prejudice." Neste Oil OYJ v. Dynamic Fuels, LLC, No. 12-1744, 2013 WL 3353984, at *2 (D. Del. July 2, 2013). Despite the fact that Cytiva and JSR may compete at some level, prejudice does not typically follow "when there are multiple active firms in the relevant market," id. at *3, as is the case here, see Ex. C at 1, 3, 4 (identifying Cytiva, Purolite Corp., and JSR Corp. as exemplary competitors in SPA-based resins). See, e.g., Bos. Sci. Corp. v. Cook Grp. Inc., No. 17-3448, 2019 WL 2511162, at *2 (S.D. Ind. June 17, 2019) (maintaining stay pending appeal, and rejecting plaintiff's undue prejudice argument absent evidence showing erosion of good will or reputational harm for plaintiffs, even where it is "uncontested" the parties are competitors).

The Court should also reject Cytiva's efforts to litigate the merits of whether it will be entitled to a permanent injunction—an approach that presumes monetary damages would be inadequate. But even if considered, the merits favor JSR. JSR's commercial activities focus on monoclonal antibodies, and Cytiva has not shown that JSR is liable for any activities related to "Fab fragments" that could justify a permanent injunction. Moreover, Cytiva's concerns about a "lock in" effect are dubious. As noted above, there are multiple competitors in the relevant market (Ex. C at 1, 3, 4); Cytiva is by far the largest, and is presently benefiting from a decades-long head start with a product portfolio that does not practice the subject matter of the asserted patents.

This factor further weighs in JSR's favor because Cytiva never sought a preliminary injunction, and delayed in bringing this infringement action for years. JSR launched the accused product in 2016 and Cytiva only sued in 2021. See, e.g., Ethicon LLC v. Intuitive Surgical, Inc., No. 17-871, 2019 WL 1276029, at *3 (D. Del. Mar. 20, 2019) (in granting stay, explaining that plaintiffs' "prejudice from a delay in trial is not severe, and any continued infringement may be compensated with damages," and explaining that plaintiffs' "delay in filing suit, decision not to seek a preliminary injunction, and delay in narrowing its asserted claims" weighed against finding undue prejudice). Cytiva's inaction undermines its claim of prejudice.

In sum, JSR respectfully requests that in light of significant potential for simplification of the case, the early stage of proceedings, and an absence of undue prejudice, the Court maintain the stay pending resolution of the Federal Circuit appeals.

Respectfully,

/s/Jeremy A. Tigan

Jeremy A. Tigan (#5239)

JAT:lo Attachments

cc: All Counsel of Record (via electronic mail; w/attachments)